K083082

7 510(k) Summary

Submitter:

Moor Instruments Ltd

Address:

Millwey

Axminster, Devon

EX13 5HU, United Kingdom

JAN 13 2009

Telephone:

(+44) 1297 35715

Fax:

(+44) 1297 35716

Contact:

Xiabing Huang

Contact title:

Technical Manager

E-mail:

xhuang@moor.co.uk

Date:

October 8th, 2008

Model Name:

moorVMS-LDF1 Laser Doppler perfusion and temperature

monito

moorVMS-LDF2 Laser Doppler perfusion and temperature

monitor

Model Number:

moorVMS-LDF1

moorVMS-LDF2

Common Name:

Laser Doppler perfusion and temperature monitor

Classification Name:

Laser surgical instrument for use in general and plastic surgery

and in dermatology, GEX, 21 CFR 878.4810

Regulatory Status:

Class II

Establishment Reg No:

8043564

Type of 510(k):

Traditional

Reason for submission:

New devices

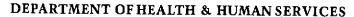
Predicate Device:

DRT4 Laser Doppler perfusion and temperature monitor

510(k) Number K011070

Moor Instruments Ltd. Millwey. Axminster: Devon: EX13-5HU-UK tel: +44 (0)1297-35715. fax: +44 (0)1297-35716 email: sales@moor.co.uk. website www.moor.co.uk. Company Registered in England No. 2209367. VAT Registration No. GB490667906









Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Moor Instruments Ltd. % Xiabing Huang Millwey Axminster, Devon EX13 5HU, United Kingdom

Re: K083082

Trade/Device Name: moorVMS-LDF1 Laser Doppler perfusion and temperature monitor

moorVMS-LDF2 Laser Doppler perfusion and temperature monitor

JAN 18 2009

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and

in dermatology

Regulatory Class: II Product Code: GEX Dated: October 8, 2008 Received: October 16, 2008

Dear Xiabing Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark of Melkers

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 083082 Device name: moorVMS-LDF1 Laser Doppler perfusion and temperature monitor

Indications for use:

The moorVMS-LDF1 and moorVMSLDF2 laser Doppler perfusion and temperature monitors are intended for simultaneous measurement of tissue temperature and blood flow in the microcirculation. The devices are intended for clinical research use.

moorVMS-LDF2 Laser Doppler perfusion and temperature monitor

	_	
Prescription Use:	Yes	
(Part 21 CFR 801	Sub	partD)

AND/OR

Over-The-Counter Use: No (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative,

and Neurological Devices

510(k) Number

K083082